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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,980	04/11/2002	Jens Berthelsen	PHRM-0373	9431
34135	7590	10/05/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,980

Applicant(s)

BERTHELSEN ET AL.

Examiner

Richard G. Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-23, 48, 53, 54 and 58-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62 is/are allowed.
- 6) ☒ Claim(s) 19, 21-23, 48, 53, 54 and 58-61 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants cancellation of claims 1-7, 9-12, 14-18, 26-30, 32-47, 49-52, 55-57 and the amendment of claims 19, 21, 23, and the addition of new claims 59-62, in the paper of 7/15/2005, is acknowledged. Claims 19-23, 48, 53, 54 and 58-62 are still at issue and are present for examination.

Claim Objections

Claims 20 is objected to because of the following informalities:

Claim 20 depends from rejected claim 19.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-23, 48, 53, 54 and 58-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 19, 21-23, 48, 53 and 54. In response to this rejection applicants have amended claims 19, 21, and 23, and added new claims 59-62 and traverse the rejection as it

Art Unit: 1652

applies to the newly amended claims. Claims 58-61 are included in this rejection for the reasons previously stated for claims 19, 21-23, 48, 53 and 54.

Applicants submit that claim 19 has been amended and new dependent claims 58-60 added to emphasize that the claimed tankyrase homolog or fragment thereof have at least one biological property of tankyrase e.g. the ability to ADP-ribosylate a suitable protein target or binding of the ANK domain to TRK1.

Applicants complete argument is acknowledged, however, not found persuasive with respect to claims 19, 21-23, 48, 53 and 54 on the basis that applicants amendment of these claims, such that the claimed polypeptide is a "tankyrase homolog or fragment thereof having at least one biological property of tankyrase" is insufficient to sufficiently define or limit the claimed genus of polypeptides such that one skilled in the art could reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. The addition of new claims 59-61 and their inclusion in this rejection is acknowledged. It is pointed out that while claims 58-60 attempt to further limit the function of the claimed polypeptides, these claims remain inadequately described with respect to structure, for the reasons stated previously and further discussed below under the rejection under 35 USC 102. Claim 61 does not limit the claimed genus functionally at all, but rather limits the claimed genus structurally.

There continues to be no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polypeptides by any identifying structural characteristics

Art Unit: 1652

or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of polypeptide molecules that are claimed continues to be a large variable genus with potentiality of comprising many different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. Applicants are reminded that tankyrase polypeptides may have a great number of biological properties, not all of which are functional. The specification discloses only one species of the claimed genus (i.e. the sequence encoding SEQ ID NO: 5) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 19, 21-23, 48, 53, 54 and 59-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those polypeptides having the amino acid sequence of SEQ ID NO: 5, which have the ability to ADP-ribosylate TRF1, does not reasonably provide enablement for those polypeptide molecules which have an undefined function or activity. The specification does not

Art Unit: 1652

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 19, 21-23, 48, 53 and 54. In response to this rejection applicants have amended claims 19, 21, and 23, and added new claims 59-62 and traverse the rejection as it applies to the newly amended claims. Claims 58-61 are included in this rejection for the reasons previously stated for claims 19, 21-23, 48, 53 and 54.

Applicants submit that claim 19 has been amended and new dependent claims 58-60 added to emphasize that the claimed tankyrase homolog or fragment thereof have at least one biological property of tankyrase e.g. the ability to ADP-ribosylate a suitable protein target or binding of the ANK domain to TRK1.

Applicants traverse this rejection in an analogous manner to the written description rejection above, on the basis that claims as amended, are now directed to tankyrase homologs or fragments thereof having at least one biological property of tankyrase.

Applicants complete argument is acknowledged, however, not found persuasive with respect to claims 19, 21-23, 48, 53 and 54 on the basis that as stated above, applicants amendment of these claims, such that the claimed polypeptide is a "tankyrase homolog or fragment thereof having at least one biological property of tankyrase" is insufficient to sufficiently define or limit the claimed genus of polypeptides. The addition of new claims 59-61 and their inclusion in this rejection is acknowledged. It is pointed out that while claims 58-60 attempt to further limit the function of the

Art Unit: 1652

claimed polypeptides, these claims remain inadequately described with respect to the claimed structure, for the reasons stated previously and further discussed below under the rejection under 35 USC 102. Claim 61 does not limit the claimed genus functionally at all, but rather limits the claimed genus structurally.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any isolated polypeptide encoded by any DNA encoding any fragment of a Tankyrase homolog having any biological activity of tankyrase. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 23 and 48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (Science 282: 1484, 1998).

The rejection was stated in the previous office action as it applied to previous claims 19, 23 and 48. In response applicants have amended claims 19, 23 and 48 and traverse the rejection as it applies to the newly amended claims.

In traversing the rejection, applicants characterize Smith et al. and argue that the present claims require a homology of greater than 90%, as opposed to the cited "best local similarity score of greater than 80%". Applicants further question the basis for the previously made statement that the polypeptide of Smith "is encoded by a nucleic acid molecule which comprises a nucleotide sequence which is a fragment of SEQ ID NO: 4". Along this same line of reasoning, applicants state "It is not understood how the longer nucleotide sequence mentioned (but not disclosed) by Smith can be considered a "fragment" of the shorter nucleotide sequence of the SEQ ID NO: 4".

Applicants are reminded of the language of the rejected claims and the subject matter of what is being claimed. Smith et al. teaches Tankyrase, a poly(ADP-ribose) polymerase (PARP) protein and this protein is encoded by a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID NO: 4 or a fragment thereof which encodes a functional domain of said peptide. It is pointed out to applicants, that the encoding nucleic acid (of the polypeptide taught by Smith et al.) comprises many nucleotide sequences, many of which are fragments of SEQ ID NO: 4 and encode a functional domain of said polypeptide.

Applicants further traverse this rejection on the basis that “ the instant application specifically excludes the nucleotide sequence encoding human tankyrase from the definition of “homologous nucleotide sequence” or variations thereof, based on the definition on page 5, lines 13-36, particularly 27-32. This is acknowledged, however non found persuasive on the basis that applicants are referring to a definition used in the specification, and applicants claims are not drawn to a “homologous nucleotide sequence” but rather to a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 4 or a fragment thereof.

For the reasons stated previously and above , Smith continues to anticipate claims 19, 23 and 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al.

This rejection was stated previously, and not specifically traversed beyond the above traversal under the 102 rejection. As applicants traversal of the above 102 rejection was not found persuasive, neither is the instant 103 rejection based on the same reasoning.

Art Unit: 1652

As discussed above, Smith et al. teach the identification, cloning and expression of Tankyrase, a poly(ADP-ribose) polymerase (PARP) protein with homology to ankyrins. Smith et al. further teach that Tankyrase is localized to telomeres and binds to telomeric repeat binding factor-1 and may act as a negative regulator of telomere length maintenance.

One of ordinary skill in the art would have been motivated to express the Tankyrase protein as part of a kit comprising and an additional components as well as instructions as to its use would have been obvious as a diagnostic for the study of DNA damage repair. Therefore, claims 53 and 54 would have been *prima facie* obvious at the time of applicants invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a long horizontal stroke extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
9/21/2005